

54 FR 43623

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

54 FR 43623

October 26, 1989

National Toxicology Program; Chemicals (7) Nominated for Toxicological Studies; Request for Comments

**SUMMARY:** On August 2, 1989, the Chemical Evaluation Committee (CEC) of the **National Toxicology Program** (NTP) met to review seven chemicals nominated for toxicology studies and to recommend the types of studies to be performed, if any. With this notice, the NTP solicits public comments on the seven chemicals.

**FOR FURTHER INFORMATION CONTACT:** Dr. Victor A. Fung, Chemical Selection Coordinator, **National Toxicology Program**, Room 2B55, Building 31, National Institutes of Health, Bethesda, Maryland 20892 (301) 496-3511.

**TEXT: SUPPLEMENTARY INFORMATION:** As part of the chemical selection process of the National Toxicology Program, nominated chemicals which have been reviewed by the NTP Chemical Evaluation Committee (CEC) are published with request for comment in the Federal Register. This is done to encourage active participation in the NTP chemical evaluation process, thereby helping the NTP to make more informed decisions as to whether to select, defer or reject chemicals for toxicology study. Comments and data submitted in response to this request are reviewed and summarized by NTP technical staff, are forwarded to the NTP Board of Scientific Counselors for use in their evaluation of the nominated chemicals, and then to the NTP Executive Committee for decision-making. The NTP chemical selection process is summarized in the Federal Register, April 14, 1981 (46 FR 21828), and also in the NTP FY 1988 Annual Plan, pages 16-19.

On August 2, 1989, the CEC met to evaluate seven chemicals nominated to the NTP for toxicological studies. The following table lists the chemicals, their Chemical Abstract Service (CAS) registry numbers, and the types of toxicological studies recommended by the CEC at the meeting.

Chemical	CAS registry No.	Committee recommendations
4-Acetylaminofluorene	28322-02-3	No additional testing.
p-Aminobenzoic acid	150-13-0	No additional testing.
Elmiron	37319-17-8	Carcinogenicity.
Ethanol	64-17-5	No additional testing.
Methanol	67-56-1	Carcinogenicity, acute and subchronic studies, Pharmacokinetics, Neurotoxicity, Immunotoxicity, Reproductive and developmental effects.
Monochloroacetone	78-95-5	No testing.
Propylene glycol methyl ether	107-98-2	Carcinogenicity.

Five of the seven chemicals have been previously selected for toxicology studies by the NTP. 4-Acetylaminofluorene was mutagenic in *Salmonella*, and was mutagenic in the mouse lymphoma assay in three independent studies. It was negative for chromosomal aberrations and positive for sister chromatid exchanges in Chinese hamster ovary cells *in vitro*. p-Aminobenzoic acid was non-mutagenic in *Salmonella*. No significant effects on mating

or fertility were observed in a continuous breeding study of ethanol in mice; however, there was a significant reduction in litter size. No teratogenic effects were observed in an inhalation teratology study of ethanol in rats. Teratogenic effects were observed in rats after inhalation exposure to methanol. No effects on fertility and reproduction were observed in a continuous breeding study of propylene glycol methyl ether in mice.

Interested parties are requested to submit pertinent information. The following types of data are of particular relevance:

- (1) Modes of production, present production levels, and occupational exposure potential.
- (2) Uses and resulting exposure levels, where known.
- (3) Completed, ongoing and/or planned toxicologic testing in the private sector including detailed experimental protocols and results, in the case of completed studies.
- (4) Results of toxicological studies of structurally related compounds.

Please submit all information in writing by November 27, 1989. Any submissions received after the above date will be accepted and utilized where possible.

Dated: October 18, 1989.

David P. Rall,

Director, National Toxicology Program.

[FR Doc. 89-25194 Filed 10-25-89; 8:45 am]

BILLING CODE 4140-01-M